SHINA CORPORATION

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AUG 0 6 2009

510K SUMMARY OF SAFETY AND EFFECTIVENESS

Revised 6-22-09

Supplement K091167

1. **Submitted by:**

Mr. YONG NAM SHIN
President

Shina Corporation
Establishment Registration No : 8040619
#1005 Owner's Tower
16-5 Sunae- Dong
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2. **Date Prepared**: April 1, 2009

3. **Device Name:**

Trade Name:	Insulin Syringes manufactured by Shina Corporation for private label (customer labels) example: Accu-Sure Insulin Syringe
Common Name:	Insulin Syringe
Classification Name:	Piston Syringe

4. **Predicate Device:**

BD Insulin Syringe:	K941657, K955235, K024112
Manufactured by:	Becton Dickinson Consumer Healthcare

5. **Device Description:**

Shina Insulin Syringes are designed for the subcutaneous injection of a desired dose of insulin. The syringe has a graduated barrel, a plunger rod and needle/hub assembly. The needle shield is colored orange. The Syringes are available in the following sizes:

1/2cc and 1cc 28 gauge x ½"
3/10cc, 1/2cc, and 1cc 29 gauge x ½"
3/10cc, 1/2cc, and 1cc 30 gauge x ½"

3/10cc, 1/2cc, and 1cc 30 gauge x 5/16"
3/10cc, 1/2cc, and 1cc 31 gauge x 5/16"

These devices operate on the principles of a piston syringe. The syringe fluid path is sterile (EO Gas sterilization), non-toxic, non-pyrogenic, and single use disposable.

6. **Intended Use:**

This device is a hypodermic insulin syringe for subcutaneous injection of insulin.

7. **Technological Characteristics:**
Shina insulin syringe and the predicate devices have the identical technological characteristics and perform as piston syringes.

8. **Performance:**
Bench tests relating to the performance of the needle length were conducted. The tests performed include needle pull-out (force), hub pull-off (force), needle angularity, needle break-off testing and dose accuracy. The results demonstrate that Shina Insulin Syringes perform equivalent to the predicate devices and are safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

AUG 0 6 2009

Mr. Yong Nam Shin
President
Shina Corporation
#1005, Owner's Tower, 16-5, Sunae- Dong, Bundang-Gu
Seongnam –Si, Gyeonggi-Do
Republic of Korea

Re: K091167
Trade/Device Name: Insulin Syringe (Manufactured By Shina Corporation)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 28, 2009
Received: July 28, 2009

Dear Mr. Shin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091167

Device Name: Insulin Syringe (manufactured by Shina Corporation)

Indications For Use: This device is a hypodermic insulin syringe for subcutaneous injection of insulin.

Prescription Use __X____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091167